AMENDMENT C

Serial Number: 09/400,365

Filing Date: September 20, 1999

Title:

PATIENT SPECIFIC CIRCULATION MODEL

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52. (amended) The method of claim 1 further comprising the step of obtaining a flow

measurement in the living subject by [magnetic resonance] phase contrast magnetic resonance

angiography.

53. The method of claim 1 further comprising the step of obtaining a flow measurement in

the living subject by a Doppler flow measurement.

54. The apparatus for modeling as in claim 12 wherein the means for measuring blood flow is

a Doppler flow measurement device.

55. (amended) The system of claim 23 wherein the flow measurement device is a [magnetic

resonance] phase contrast magnetic resonance angiography system.

REMARKS

Claims 1-28 and 52-55 are now pending in the application. Applicant appreciates the

examiner's renumbering of claims 52-55 and cancellation of claims 29-50. The specific grounds

of rejection contained in the office action are addressed in turn below.

Request for Information under 37 C.F.R. 1.105

Applicant has searched for but is unable to obtain any further documentation relating to

the Charbel #1 and Charbel #2 presentations requested by the examiner.

Objections to the Specification

Applicant has amended the title and disclosure herein in a manner believed to overcome

the examiner's objections.

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## Rejections Under 35 U.S.C. § 112

Claims 25-28 were rejected under section 112, first paragraph, while claims 21-28 and 55 were rejected under section 112, second paragraph. Applicant has amended those claims herein in a manner consistent with the specific suggestions contained in the office action in order to overcome the rejections.

## Rejections Under 35 U.S.C. § 102 and 103

All of the pending claims have been rejected under 35 U.S.C. 102(b) and/or 103 in view of the Charbel #1, Charbel #2, Karplus, Foutrakis and/or Ortega references. The rejections are traversed, and reconsideration is respectfully requested. As amended herein, independent claims 1, 12, and 23 now recite a method, apparatus, or system in which a model simulating the fluid dynamics of the circulatory system is adapted to conform to the anatomy of a particular subject and is then corrected based upon a flow measurement obtained from the subject and a flow calculated by the model. (Note that for clarity, applicant uses the phrase "adapting the model" to refer to conforming the model to a patient's particular anatomy and the phrase "correcting the model" to refer to the adjustment of model parameters such as resistance or capacitance. As explained below, the phrase "forcing the model" has a quite different meaning.) Applicant has determined experimentally that correcting the model in this manner produces a more patientspecific circulatory model which is able to more accurately predict blood flows in the patient. A particular embodiment of this method of model correction which is disclosed in the specification involves multiplying a vessel resistance value in the model by a ratio of the calculated and measured flows. The correction is then applied iteratively as the model is forced with an appropriate forcing function. Applicant finds no teaching or suggestion of correcting a circulatory model based upon calculated and measured flows in any of the cited references. Prior methods of simulating the circulatory system have relied solely upon the geometry of the circulatory system, as determined by imaging, to establish parameters of the simulation. Although the Karplus reference, for example, discusses validating a model of an aneurysm by comparing simulated fluid flow fields with experimental data, there is no discussion of actually correcting the model in accordance with the data, much less how one would go about performing

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the correction. Furthermore, the Karplus reference deals only with a generalized fluid flow model of an aneurysm, and not with a patient-specific circulatory model. Applicant therefore

submits that claims 1, 12, and 23 are patentable over the prior art references of record.

Claims 2-11, 13-22, and 52-55, as amended, are all dependent claims that add limitations to one of the independent claims 1, 12, or 23. For the reasons stated above, therefore, these claims are asserted to be patentable over the prior art of record. In addition, however, applicant believes the limitations recited by those claims to be patentably significant at least in the context of a circulatory model as now recited by claims 1, 12, or 23. Certain specific points raised by the examiner in the office action with regard to those claims are addressed below.

Claims 15, 52, and 55 recite limitations relating to the measurement of blood flow with phase contrast magnetic resonance angiography (PCMRA). This is distinct from magnetic resonance imaging (MRI) or MRI angiography. Applicant finds no teaching relating to PCMRA in either of the Charbel #1, Charbel #2, Karplus, Foutrakis, or Ortega references. Claims 53 and 54 recite limitations relating to Doppler measurement of blood flow. Although Doppler measurement of blood flow is well-known generally, applicant asserts its use to be patentably significant in the context of measuring blood flow in a vessel corresponding to a flow calculated by a fluid dynamics model in order to correct the model.

Claims 10-11 and 21-22 recite limitations relating to the manner in which the model of the circulatory system is forced. By "forcing" the model or simulation, as the term is used in the specification, is meant the calculation of flows and pressures by the model in accordance with a forcing function applied to the model that defines a flow or pressure at a specific location. For example, a forcing function may be a pressure-time signature at the base of the aorta which the model then propagates throughout the rest of the modeled circulatory system by calculation of local flows and/or pressures. Prior to the present amendment, applicant had amended claims 1-11 to recite that the simulation of the circulatory system is forced with one or more flow parameters corresponding to a flow measurement obtained from the living subject, amended claims 12-22 to recite a means for forcing the model of the circulatory system with one or more flow parameters corresponding to a flow measurement obtained from the living subject, and amended claims 23-28 to recite a blood flow measurement device for obtaining a flow

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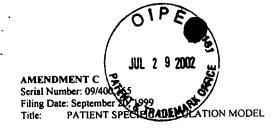
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measurement from the living subject so that the model may be forced with one or more flow parameters corresponding thereto. Applicant respectfully disagrees with the examiner that such features are taught or suggested by the aforementioned references, either implicitly or explicitly. Applicant is unable to find in any of the cited references an explicit or implicit suggestion for forcing a computerized circulation model with an actual flow measurement of the living subject whose circulation is being modeled. The point may be rendered moot for purposes of the present examination, however, as applicant has amended independent claims 1, 12, and 23 to recite additional subject matter which is believed to patentably define over the prior art of record as explained above. Nevertheless, dependent claims 10 and 21 have been amended to recite a method and apparatus, respectively, in which a circulation model is forced with a flow measurement taken from the living subject, and applicant believes the recitation to be patentably significant. Applicant believes the recitations of claims 11 and 22, which relate to a forcing the model with a forcing function based upon a prototypical measurement, to also be patentably significant in the present context.





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## **CONCLUSION**

In view of the foregoing amendments and remarks, applicant believes the application is in condition for allowance and respectfully requests such action. Please charge any fees deemed necessary to Deposit Account 19-0743. The examiner is invited to telephone applicant's attorney, J. Kevin Parker, Reg. No. 33,024, at 847-432-7302 to discuss any questions that may remain with respect to the present application. Applicant's attorney would also appreciate the examiner calling to discuss the case prior to issuing the next office action.

Respectfully submitted,

Fady Charbel et. al,

By their Representatives,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to

Commissioner of Patents, Washington, D.C. 20231 on July 3, 2002.

Name MAN M. MILE

Signature